REMARKS

Rejections Under 35 U.S.C. § 112

Claim 17 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (Office Action, page 3).

Applicants acknowledge with appreciation the indication that claim 17 is enabled "for a method of inducing a prophylactic immune response" on page 3 of the Official Action. Accordingly, while applicants respectfully disagree with the rejection, to simplify the issues and applicants have broadened claim 17 back to its originally presented language by removing the objectionable phrase "to bacterial or viral infection". Accordingly, it is respectfully submitted that this rejection should be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 14, 16-19 and 28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rosok *et al.* (U.S. Patent No. 4,834,976) in view of Lenney *et al.* (*J. Pharm. Sci. 66*:702 (1997)) as evidenced by Hood et al. (Office Action, page 6). Applicants respectfully traverse this rejection.

Rosok is clearly non-analogous art because Rosok concerns ***passive immunity*** while the present invention concerns ***active immunity.*** The distinctions between these two types of immunity have long been recognized. Indeed, the 25th Edition of *Dorland's Illustrated Medical Dictionary* (1974) defines these two terms as follows:

> "***active i.,*** acquired immunity attributable to the presence of antibody or of immune lymphoid cells formed in response to antigenic stimulus ...
> ***passive i.,*** acquired immunity produced by the administration of preformed antibody or specifically sensitized lymphoid cells."

The claimed invention speaks of an immune response developed in response to administration of an immunogen and not a preformed antibody, and hence is concerned with active immunity and not passive immunity.

It is well settled that—unlike active immunity—passive immunity is ***temporary***. For example, the University of Auckland Immunisation Advisory Center compares active and passive immunity as follows:

> Active immunity is protection that is produced by the person's own immune system. This type of immunity is usually permanent.
>
> Passive immunity is protection by products produced by an animal or human, and transferred to another human, usually by injection. Passive immunity often provides effective protection, but this protection wanes (disappears) with time, usually a few weeks or months.

University of Auckland, Immunisation Advisory Centre, ***Specific Immunity*** (2008) (copy enclosed). Indeed, passive immunity is frequently referred to as "temporary passive immunity" in the issued United States patent literature, as follows:

> Anti-PorB antibodies can also be administered to provide ***temporary, passive immunity*** against chlamydial infections (e.g., to inhibit chlamydial infection and/or disease symptoms that can result from such infection). US Patent No. 7,105,171.
>
> The intravenous administration of influenza-specific polymeric IgA induces ***temporary passive immunity*** against the virus in nonimmune mice as IgA is transported from the serum into the nasal secretions Renegar et al., J. Immunol., 146:1972-1978 (1991)). US Patent No. 6,271,202.
>
> When the antibodies of the invention are used to provide ***temporary passive immunity,*** such as when the individual is a large mammal such as a human who may be exposed to ricin toxin in a military action. The antibodies are more advantageously administered a soon as possible after exposure to ricin. US Patent No. 5,626,844.
>
> The preferred anti-rabies antisera of the invention are those prepared using the preferred vaccines of the invention. As indicated supra, antisera themselves or antibody fractions isolated from said antisera can be used to confer ***temporary, passive immunity*** against rabies virus on a mammal exposed to the virus and, thereby, prevent the development of rabies in said mammal. US Patent No. 4,652,629.

The **Hood et al.** reference (partially explaining the "network theory" of immune responses) is cited to apparently suggest that the antibodies used to produce passive immunity as described in **Rostok** contain "idiotypes" that will in turn produce anti-idiotypic antibodies, which will then in

turn "provide treatment or prophylaxis of *P. aeruginosa* infection." There are at least two problems with this hypothesis:

First, if anti-idiotypic antibodies were produced, they would necessarily bind to the idiotypic antibodies intentionally administered and destroy the functioning thereof. Accordingly, the Rostok and Hood references cannot be combined with one another without destroying the functioning of Rostok.

Second, the hypothesis that a passive immunization procedure will produce active immunity is inconsistent with the overwhelming evidence in the art, which *(a)* dramatically distinguishes between these two procedures, and *(b)* recognizes passive immunity as temporary as compared to active immunity.

Finally, the portion of the Hood reference relied upon refers only to the "network theory" of immunity. It does not suggest or describe inherent features of passive immunity. The network theory is indeed described as a highly hypothetical one in which a "network of interactions that ***could potentially*** involve the entire immune system" is described, the connections of which "***could be*** either open-ended or closed. The portion of the text provided concludes on page 373 with the statement that ***"two major unresolved questions that may be related remain"*** but the further portions of the text setting forth these questions is not provided. If this rejection is maintained after consideration of the points raised above, then a complete copy of those portions of the Hood et al. reference describing the network theory is requested.

Lenney *et al.* disclose experiments showing that Compound 48/80 has some antimicrobial activity. Lenney *et al.* are silent regarding immunogens, combining Compound 48/80 with other agents, or using Compound 48/80 to raise a therapeutic immune response in a subject. Nothing suggests that Compound 48/80 has adjuvant properties. Accordingly, this reference cannot be combined with the references above.

Conclusion

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

Kenneth D. Sibley.
Registration No. 31,665

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

704161